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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,917	01/24/2001	Alain P. Vicari	SF0896K	5028

24265 7590 12/22/2003

SCHERING-PLOUGH CORPORATION  
PATENT DEPARTMENT (K-6-1, 1990)  
2000 GALLOPING HILL ROAD  
KENILWORTH, NJ 07033-0530

EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 12/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

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**Advisory Action****Application No.**

09/768,917

**Applicant(s)**

VICARI ET AL.

**Examiner**

Anne Marie S. Wehbe

**Art Unit**

1632

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 03 November 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see attached.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 21-24, 26-36, 69.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

**Attachment to Advisory Action**

**2. cont.** The proposed amendment introduce new limitations into the claims, specifically the limitation wherein the antigen and chemokine are not physically linked as a fusion protein, and as such would require additional search and consideration.

**5. cont.** Applicant's arguments regarding the rejection under 35 U.S.C. 102 are based on the proposed claim amendments which have not been entered. As such, these arguments are not found persuasive in overcoming the rejection of record over claims 21-24, 26-32, 35-36, and 69 under 35 U.S.C. 102(b).

Applicant's arguments regarding the rejection of claims 21-24, 26-36, and 69 under 35 U.S.C. 103(a) have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed briefly below.

The Office has previously acknowledged that Caux et al. may not be relied upon for teachings MCP-4. However, as stated in previous office actions, Caux et al. may be relied upon for teaching methods of using chemokines in combination with antigens for directing the migration of antigen presenting cells, including dendritic cells, to lymphoid organs in vivo in order to increase immune responses (Caux et al., columns 4-6, and 18-19). Caux et al. teaches several different chemokines including MIP-3 $\alpha$ , MIP-1 $\beta$ , and RANTES, which are capable of attracting and/or activating antigen presenting cells (Caux et al., columns 1-4). Thus, Caux et al. already provides a reasonable expectation of success in combining chemokines and antigens to stimulate immune responses. Luster et al. supplements Caux et al. by teaching the administration of human MCP-4 in the form of a protein or a nucleic acid vector in order to stimulate immune responses in a mammal (Luster et al., pages 4-5, particularly page 5, lines 9-12). Luster et al. also teaches the MCP-4 is chemotactic for antigen presenting cells such as monocytes (Luster et al., pages 34-35). Dieu-Nosjean et al. further supplements Luster et al. by teaching that MCP-4 is capable of causing the activation and migration of dendritic cells (Dieu-Nosjean et al., page 255, Table 2). Thus, based on the known properties of MCP-4 in activating and attracting dendritic

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cells, and stimulating immune responses, the skilled artisan would have been motivated to use MCP-4 in the methods of stimulating antigen-specific immune responses taught by Caux et al.

Regarding applicant's contention that the instant specification demonstrates unexpected results, the MPEP states that the arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716,718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results. MPEP 716.01(c). Therefore, applicant's arguments regarding the Li et al. reference and "unexpected results" are not compelling in the absence of evidence in the form of a declaration or affidavit.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 872-9306.

**Please note that the United States Patent and Trademark Office will begin to move to the new campus in Alexandria, Virginia, in December 2003. The examiners of Art Unit 1632 will be moving in January 2004. As of January 13, 2004, this examiner's phone number will be (571) 272-0737, and that of the examiner's supervisor will be (571) 272-0734.**

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D  
PRIMARY EXAMINER

